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Bernard J Durkan, T.D.
Dáil Éireann,
Leinster House,
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Dublin 2.

5th April 2022

PQ: 14959/22

To ask the Minister for Health the amount and percentage of the amount spent on medicines by the State that related to biosimilar medicines; his plans to increase the use of biosimilar medicines in Ireland; the saving achieved in biosimilar medicines in each of the past five years in tabular form; and if he will make a statement on the matter. -Bernard J. Durkan

Dear Deputy Durkan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 14959/22), which you submitted to the Minister for Health for response.

A suite of measures are available to the HSE for the management of current and future medicines expenditure on biological medicines. These measures include HSE Medicines Management Programme (HSE-MMP) led best-value biological medicines initiatives, pricing framework agreements between the State and the pharmaceutical industry and procurement of biological and biosimilar medicines in hospital settings supported by the HSE National Drugs Management Programme Dynamic Purchasing System.

Best-Value Biological Medicine Initiatives

Best-value medicines (BVM) and best-value biological medicines (BVB) initiatives are a cost saving measure utilised by the HSE. Best-value medicines are often provided to the HSE at a lower cost than the originator brands of medicines. This provides the HSE with an opportunity to reduce the cost of providing such medicines to patients. Further information in relation to potential best-value medicine initiatives for 2022 are available at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/best-value-medicines/mmp-bvb-and-bvm-processes-2022.pdf

From 1 February 2020, it is HSE policy that all adult patients who are commencing treatment with Adalimumab or Etanercept (biologic treatments for autoimmune conditions) should be prescribed a best-value biological medicine. The HSE Medicines Management Programme is responsible for determining the BVB.

Of note, as of March 2022, over 18,200 patients had been prescribed one of the identified BVB medicines for Adalimumab or Etanercept. In February 2022, 73% of patients in receipt of Adalimumab 40 mg pre-filled pen or syringe, and 65% of patients in receipt of Etanercept 25/50 mg pre-filled pen or syringe under the High Tech Arrangements received a BVB medicine.

The HSE has identified the following biological medicines for which it may initiate a BVB / BVM process in 2022: Adalimumab; Etanercept; Filgrastim; Follitropin alfa; Pegfilgrastim; and Teriparatide. The formal consultation process for Teriparatide has already begun with submissions from all relevant stakeholders to be submitted by 4th May 2022. Information on the consultation is available on the HSE-MMP website: https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/consultation/

In 2022, the HSE will continue to evaluate the therapeutic areas where there is potential to identify BVB medicines to support their safe, effective and cost-effective use. Engagement with clinicians will also be carried out to support the prescribing of BVB medicines. Expenditure on BVB medicines will continue to be monitored.

New Framework Agreements between the State and the Pharmaceutical Industry

The State has agreed two new multiannual agreements with the Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI):

- Framework Agreement on the Supply and Pricing of Medicines (i.e., the 2021 IPHA Agreement)
- Framework Agreement on the Supply and Pricing of Generic, Biosimilar, and Hybrid medicines (i.e., the 2021 MFI Agreement)

These new framework agreements on the supply and pricing of medicines will contribute to the sustainable funding of new and existing medicines and to deliver additional savings to the State. These savings will be achieved via a number of measures outlined in these agreements including enhanced price reductions for off-patent medicines and increased rebate contributions for on-patent medicines.

With specific regard to biological medicines these framework agreements ensure:

- Relevant patent-expired non-exclusive biologic medicines are reduced to 62.86% of their 31st July 2016 ex-factory price. In addition, the supplier pays a rebate of a sum equal to 12.5% of the value of the reduced ex-factory price. (https://www.hse.ie/eng/about/who/cpu/ipha-price-reduction-2022/)
- The price of each medicine that becomes a patent-expired non-exclusive biologic medicine after 1st January 2022 are reduced to 62.86% of the ex-factory price of that medicine as of the 1st October 2021. In addition, the supplier pays a rebate of a sum equal to 12.5% of the value of the reduced ex-factory price.

- On 1st of March 2022, the price of each existing biosimilar medicine to be reduced to 55% of the 31st of July 2016 price of the reference originator. (https://www.hse.ie/eng/about/who/cpu/mfi-price-reduction-2022/)
- A new biosimilar medicine for which an application is made to be priced at no greater than 55% of the 1st October 2021 price of the equivalent branded original medicine.

The HSE National Drugs Management Programme Dynamic Purchasing System

The HSE Drugs Management Programme has developed a strategy for the Procurement of Medicines in Acute and non-Acute Hospitals available at: https://www.hse.ie/eng/about/who/national-drugs-management-programme/procurement-of-medicines-strategy-document.pdf

The strategy provides for the introduction of a National Dynamic Purchasing System (DPS) as the preferred model to facilitate compliant procurement of medicines by HSE and HSE-funded hospitals. Accordingly the National Dynamic Purchasing System has been used by hospitals for procurement of biosimilars.

Prescribing of best-value biological and biosimilar medicines is leading to significant savings for the HSE and additional best-value medicine initiatives are planned to further contribute to the sustainable funding of new and existing medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service